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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group:	3738
Customer No.:	23643
Confirmation No.:	9094
Application No.:	10/044,031
Invention:	**Purified Submucosa Graft Material**
Applicant:	Stephen F. Badylak et al.
Filed:	January 11, 2002
Attorney Docket:	3220-69262
Examiner:	Paul B. Prebilic

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

on March 10, 2008

Rebecca Ball
(Signature)

Rebecca Ball
(Printed Name)

SUBMISSION UNDER 37 C.F.R. §§ 41.202(a) and (d)

In response to the Office Action mailed on September 10, 2007 in the above-captioned application, Applicants make this submission. The Examiner pointed in the office action to Rule 41.202, in particular sections (a)(4) and (d), covering the requirement to make a showing of priority. The present application claims the ***same priority date*** as the patent or published application claiming interfering subject matter (*i.e.*, U.S. Patent No. 6,206,931) so it is Applicants' understanding that a priority showing under Rule 41.202(a)(4) and (d) is not required for the present application.

Applicants suggest an interference with U.S. Patent No. 6,206,931, and one of the issues to be decided in the interference will be *determination of the correct inventive entity for the inventions that are now claimed in the above-captioned application and in U.S. Patent No. 6,206,931.* In *Sewall v. Walters*, the Federal Circuit stated that "[i]n this case, Sewall admits that he did not independently conceive the subject matter recited in the count. Instead, Sewall

contends that he aided Walters in the conception of that subject matter, and therefore, that he is a joint inventor and should be designated as such pursuant to 35 U.S.C. § 116. This case therefore comes to us in the context of an originality contest as opposed to a priority contest. *Applegate v. Scherer*, 332 F.2d 571, 573 n. 1, 141 USPQ 796, 798 n. 1 (CCPA 1964) ("[I]n an originality case the issue is not who is the first or prior inventor, but who made the invention."). The "inventorship" issue to be decided is thus merely who conceived the invention for which patent protection is sought, and not who first conceived that invention." *See Sewall v. Walters*, 21 F.3d at 415, 30 USPQ2d at 1358 (Fed. Cir. 1994).

Sewall v. Walters was an interference case decided by the Board of Patent Appeals and Interferences, and the Board's decision was reviewed by the Federal Circuit. The Federal Circuit in *Sewall v. Walters* concluded that an interference proceeding can be an originality contest. The interference that Applicants suggest will be at least, in part, an originality case and the issue of originality (*i.e.*, proper inventorship) will be decided. Because the present application claims the ***same priority date*** as U.S. Patent No. 6,206,931 (the '931 patent) it is Applicants' understanding that a priority showing under Rule 41.202(a)(4) and (d) is not required for the present application.

Applicants' undersigned attorney spoke on the phone with Examiner Prebilic about this issue and Examiner Prebilic said to make this point in Applicants' last response to office action filed in this application. Accordingly, Applicants made this point in the last response to office action filed and Applicants believe that the Examiner's present request for a priority showing is improper. However, after the filing of Applicants' last response, Examiner Prebilic repeated the same request in the office action issued on September 10, 2007 so, although Applicants believe that this request is improper, Applicants respond as follows.

37 C.F.R. § 41.202(a)(1)-

Applicants suggest an interference with U.S. Patent No. 6,206,931.

37 C.F.R. § 41.202(a)(2)-

Applicants believe that claims 1-8 and 10-20 interfere with claims of the '931 patent. Applicants propose pending claims 1-8 and 10-20 as counts. As such, claims 1-8 and 10-20 are the same as the proposed counts.

37 C.F.R. § 41.202(a)(3)-

Count	Corresponding Claim in U.S. Application No. 10/044,031	Corresponding Claim in U.S. Patent No. 6,206,931
Claim 1	Claim 1	Claim 1
Claim 2	Claim 2	Claim 2
Claim 3	Claim 3	Claim 3
Claim 4	Claim 4	Claim 5
Claim 5	Claim 5	Claim 6
Claim 6	Claim 6	Claim 7
Claim 7	Claim 7	Claim 19
Claim 8	Claim 8	Claim 20
Claim 10	Claim 10	Claim 21
Claim 11	Claim 11	Claim 22
Claim 12	Claim 12	Claim 26
Claim 13	Claim 13	Claim 29
Claim 14	Claim 14	Claim 30
Claim 15	Claim 15	Claim 31
Claim 16	Claim 16	Claim 34
Claim 17	Claim 17	Claim 35
Claim 18	Claim 18	Claim 36
Claim 19	Claim 19	Claim 37
Claim 20	Claim 20	Claim 38

The claims in the instant application interfere with the claims of the '931 patent because the claims of the instant application are either identical to the claims of the '931 patent or there are no colorable differences.

37 C.F.R. § 41.202(a)(4)-

Although Applicants believe that they will prevail on priority for at least independent claims 1, 11, and 16 (claims 1 and 11 are identical to claims 1 and 22, respectively, of the '931 patent), Applicants wish to reiterate that Applicants believe that this interference should be an originality contest rather than a priority contest. *See Sewall v. Walters*, 21 F.3d at 415, 30 USPQ2d at 1358 (Fed. Cir. 1994). As a consequence, Applicants believe that the request for a response under 37 C.F.R. § 41.202(a)(4) is improper or, in the alternative, should be held in abeyance until the claims are found allowable. Nonetheless, for at least independent claims 1, 11, and 16, Applicants believe that they will prevail on priority because Applicants have documentary evidence (see Exhibit A submitted with this response) that Applicants prepared the claimed graft construct before the earliest priority date of the '931 patent. Applicants have documentary evidence that a construct within the scope of claims 1, 11, and 16 was prepared by a protocol developed by Applicants and exhibited an endotoxin level of less than 12 endotoxin units per gram as determined by the Limulus Amebocyte Lysate Test (the LAL test), a well-accepted test for detecting and quantitating bacterial endotoxins associated with biological materials. A negative LAL test result, based on the protocol used in the assay that provided the results shown in Exhibit A, is indicative of an endotoxin level of less than 12 endotoxin units per gram. The document submitted herewith as Exhibit A has a date (redacted) that is before the earliest priority date of the '931 patent.

37 C.F.R. § 41.202(a)(5)-

This section is not applicable because claims 1-8 and 10-20 are originally filed claims.

37 C.F.R. § 41.202(a)(6)-

It is Applicants' understanding that this section is not applicable because the above-captioned application and the '931 patent have the same disclosure and dates of constructive reduction to practice. However, Applicants have previously provided a response under 37 C.F.R. § 1.607(a)(5) and Applicants provide a supplementary chart below.

Count	Support
Claim 1	Same as corresponding disclosure in '931 patent family
Claim 2	Same as corresponding disclosure in '931 patent family
Claim 3	Same as corresponding disclosure in '931 patent family
Claim 4	Same as corresponding disclosure in '931 patent family
Claim 5	Same as corresponding disclosure in '931 patent family
Claim 6	Same as corresponding disclosure in '931 patent family
Claim 7	Same as corresponding disclosure in '931 patent family
Claim 8	Same as corresponding disclosure in '931 patent family
Claim 10	Same as corresponding disclosure in '931 patent family
Claim 11	Same as corresponding disclosure in '931 patent family
Claim 12	Same as corresponding disclosure in '931 patent family
Claim 13	Same as corresponding disclosure in '931 patent family
Claim 14	Same as corresponding disclosure in '931 patent family
Claim 15	Same as corresponding disclosure in '931 patent

	family
Claim 16	Same as corresponding disclosure in '931 patent family
Claim 17	Same as corresponding disclosure in '931 patent family
Claim 18	Same as corresponding disclosure in '931 patent family
Claim 19	Same as corresponding disclosure in '931 patent family
Claim 20	Same as corresponding disclosure in '931 patent family

37 C.F.R. § 41.202(d)-

Although Applicants' earliest constructive reduction to practice date is not later than the earliest constructive reduction to practice date for the '931 patent, Applicants have discussed, under the heading 37 C.F.R. § 41.202(a)(4) above, why Applicants will prevail on priority.

Respectfully submitted,

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